IMPROVED DETECTION OF HUMAN BREAST LESIONS FOLLOWING EXPERIMENTAL TRAINING II: A MEDICAL STUDENT REPLICATION

Lealyn Carol Pennypacker

1985

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A thesis submitted to the Yale University School of Medicine in partial fulfullment of the requirements for the degree of Doctor of Medicine

by

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ABSTRACT

IMPROVED DETECTION OF HUMAN BREAST LESIONS FOLLOWING EXPERIMENTAL TRAINING II: A MEDICAL STUDENT REPLICATION

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This study was designed to determine the efficacy of incorporating Mammatech technology into the training of breast examination to medical students. Thirty (30) first and second year medical students were voluntarily recruited for participation in the study. Experimental group students were instructed in the basic principles of Mammatech technology through the use of realistic, human breast models containing simulated lesions. Control group students received breast examination training via the technique recommended by the American Cancer Society. All training sessions were incorporated into the Gynecologic Teaching Assistants Program at Yale University School of Medicine. When stable measurements of clinical performance were obtained, experimentally trained students detected a significantly greater number of abnormal breast lesions as compared to matched controls, in patients referred to clinic for breast evaluation. In addition, the false negative detection frequency of experimental students was significantly lower than controls. Overall sensitivity measures in the experimental group were comparable to those previously reported in experienced physicians. If trained to proficiency on the breast models, students could theoretically be expected to perform breast examinations with an 80% sensitivity rate. These data suggest that the Mammatech technology may substantially improve the training of professionals in breast examination.

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I. Review of the Literature

One out of eleven women in this country will develop breast cancer within her lifetime. As the leading cause of cancer death among women between ages 15 and 74 years, primary carcinoma of the breast claimed more than 37,000 lives in 1983, with approximately 114,000 new cases diagnosed.

Although some researchers cautiously point out that it is premature to conclude that early treatment of breast cancer can lead to cure [1,2,3], several studies have documented the importance of early diagnosis and treatment in an attempt to minimize the morbidity and mortality associated with the disease. Fischer [4] and his associates studied 2578 breast cancer patients within the National Surgical Adjuvant Breast Project, and observed that the larger the primary tumor: 1) the more likely axillary nodes will be involved, 2) the more likely four or more nodes will be involved, as opposed to one to three nodes, and 3) the greater will be tumor recurrence and mortality rates.

Similar results demonstrating the association between size of primary tumor and likelihood of axillary node involvement have been obtained by many other researchers[5,6,7]. If primary breast cancer is diagnosed and treated before the spread of malignant cells to regional or distant sites, five-year survival rates approach 75-85% according to the findings of the American College of Surgeons,[8] and the National Cancer

Institute [9]. Given only 10-12% five-year survival rates with distant (metastatic) disease [8,9], many would agree with Cole's conclusion that, "At present the only demonstrably valid method for reducing breast cancer mortality is early detection and treatment of the disease." [10]

Many efforts have been made in recent years to develop accurate and safe methods for early detection of breast cancer. The problem of determining which method, or combination of methods, is most efficacious (with the least associated risk) has engaged numerous researchers in the past two decades. The controversy remains unsettled. Under primary investigation are various imaging techniques such as thermography, ultrasound, and mammography. In addition, standard methods of physical examination, both in the form of physician examination and breast self-examination, continue to be a focal point of many screening programs.

Of the above mentioned methods, thermography and ultrasound are presently experimental techniques and have not been widely used for clinical screening and diagnosis. The major advantage of these is the lack of radiation exposure to the patient, but as yet there is no incontrovertible evidence to support their efficacy in breast cancer screening. Sickles et al [11] examined 1,000 women with both sonography (ultrasound) and mammography, and concluded that state-of-the-art mammography was superior in detecting non-palpable breast masses, and that sonography was severely limited by the inability to detect

microcalcifications (often the only indicator of non-palpable breast cancer). Sonography was, however, effective in distinguishing cystic vs. solid masses, and continues to be widely used for this purpose. Similarly, Gohegan[12] showed that thermography was associated with a 39% sensitivity rate, and only a 91% specificity rate. These data imply that approx. one out of ten breast cancers will be missed by thermography, and almost two thirds of the exams will reveal a diagnosis of cancer that is not, in fact, a malignancy at all. Gohegan concluded, as have others, that thermography should play only a minor role in breast cancer screening because of the unacceptably high frequency of false positive examinations. While ultrasound and thermography show great promise for the future, these imaging techniques will require further development before they can be proven efficacious in the screening of women at risk for developing breast cancer.

The most accurate, and certainly the most controversial of the breast imaging techniques is mammography. First performed by a German surgeon, Salomon, in 1913, mammography was not recognized as an acceptable diagnostic procedure in the U.S. until the mid-1950's. Since its early stages of development, the mammographic technique had been significantly refined and improved with a resultant increase in sensitivity, as well as decreases in radiation exposure. Dodd [13], in a recent review of the data from both the Health Insurance Plan (HIP) study of 1966 [14], and the Breast Cancer Detection Demonstration

Project (BCDDP) of 1982 points out that there has been a substantial improvement in the quality of mammography over the past two decades. These improvements are particularly apparent in the study of women between ages 40-49 years, in which mammograms were positive in only 38% of known cancers in the HIP study, while a 91% true positive rate was noted in the BCDDP data. In the Columbia, Missouri section of the BCDDP study, Gohegan [12] demonstrated a 58% true positive rate for Xeromammography, but only one out of one hundred cancers were missed by the mammographic screening of 10,187 asymptomatic women. Exact figures vary from one study to the next, but most experts in the field would not challenge the fact that mammographic imaging is the most successful means of detecting small (less than 1 cm.), non-palpable breast lesions. Proponents of mammography, such as Dr. Philip Strax of the HIP study in New York, claim that no other detection modalities currently available (ultrasound, thermography, transillumination) are able to detect non-palpable masses accurately. Dr. Strax further points out that with radiation doses reduced to 0.02-0.03 rads per examination, the risks of mammography are "very small, most likely negligible, and probably not even measureable." [15] However, opponents of mammography insist that, "breast cancer screening can save lives, at least in the short run, but the contribution of x-ray mammography to that initial benefit is not clear."[16] Despite the specifics of the debate, it must be recognized that mammography

remains a relatively expensive procedure (average cost: $100.00 per diagnostic exam, $68.00 per screening exam),[17] and is currently not accesible to many women at risk because of financial considerations. Until the safety of mammography is clearly established and accepted by the professional and lay communities, and the cost of the exam is reduced, it is not likely to become widely accepted as a feasible technique for breast cancer screening.

Lastly, physical examination has been intensively investigated as a safe, cost-effective, easily accesible technique for breast cancer screening. Breast self-examination (BSE) and examination by physicians have been independently analyzed and compared in numerous studies. As with mammography, a consensus has not been established concerning the true efficacy of these techniques, but the majority of the evidence clearly supports their crucial role in breast cancer screening.[14, 18-31] Greenwald et al [21] demonstrated that BSE and routine physician examination led to an 18.8% and 24.4% reduction respectively in the five-year mortality rate of breast cancer in 293 women studied. Tumors found during routine examination of the breast were on the average 20% smaller (23.9 mm vs. 30.0mm) than tumors accidently discovered, and there was a highly significant shift toward earlier stage of disease at diagnosis. Foster [20], in a study of 1,004 women with newly diagnosed breast cancer, concluded that women who practiced monthly (or several times annually) BSE had a 75% five-year survival rate with average primary tumor

size of 2.1 cm., while those women that never practiced BSE suffered a 57% five-year survival rate associated with primary tumor size of 3.2 cm. Similar results have been found by other investigators,[18,22] some favoring physician examination over BSE [19,23]. Nonetheless, all data reviewed clearly supported Venet's conclusion that, "the clinical examination is an essential component of the current screening program: without such an examination, a significant proportion of the cancers (45% in his data) would have been missed, a large majority of which had no axillary node involvement." [23]

Despite the fact that at least 80% of breast masses are discovered by women themselves [12,15,32], the above data, and BSE in particular, have recently come under new scrutiny. Critics point out that most women do not perform BSE, and those that do, do so incorrectly.[33-35] Gallup poll data from 1,007 women randomly surveyed clearly reflect current inadequacies in the prevalence and accuracy of performance of BSE among women in the U.S. While 77% of the women polled reported awareness of BSE, only 47% reported examining themselves at least once in the previous 12 months, and less than one fifth performed regular monthly examinations. Shelley [35] estimates that even fewer women, approximately 10% in his study, perform self-examination monthly and proficiently. He concluded that, "until researchers systematically address the issue of the degree to which women assimilate breast cancer self-detection technology, they cannot resolve the issue of efficacy of the

technology itself."

A multi-disciplinary group of researchers (physicians, engineers, psychologists) at the University of Florida have directed their efforts towards resolving exactly those issues raised by Shelley.[35] Studies performed by the Breast Lump Detection Project [24-29] have resulted in: 1) the establishment of psychophysical parameters of the sensori-motor skills of lump detection [29], 2) the development of a realistic human breast model embedded with simulated tumors [24], and 3) the development of a training technology (using both the models and the womens' own breast tissue) specifically designed to teach the skills necessary for the performance of accurate BSE. Through the use of this technique of teaching BSE, women can theoretically be trained to detect lesions less than 2 mm. in size [25], significantly smaller than the average size of masses currently being found by practicers of BSE [4,18-21]. In a review of 428 women trained via the above described method, twenty-six suspicious breast lumps were self-detected, representing a detection rate of approx. 6.1%. Data generated at the nearby BCDDP in Jacksonville, Fla. reported screening 10,418 women in which mammography revealed 535 suspicious masses, corresponding to a detection rate of 5.3%. Although previous studies have suggested that mammography was superior to clinical examination in the detection of breast masses [12,32], Pennypacker concluded that the above finding, "implies that our method of instructing BSE appears

as aggressive a screen as mammography while lacking the attendant inconvenience, expense, and risk." [25]

In addition to its establishment as a proficient method of training BSE, there is preliminary evidence that the Mammacare Method (the name under which the above technology is now patented and marketed by the Mammatech Corporation) may also prove useful in instructing physicians and para-professionals in breast examination.[27]

Given that approximately 94% of breast masses are potentially palpable [7], and that the percentage of such masses first detected by physicians has gradually increased since the mid-1930's [30], the importance of improving the breast examination skills of physicians becomes clearly relevant. In a recent pilot study conducted at the Univ. of Fla. School of Medicine, those medical students given breast examination training on the Mammatech models detected significantly more breast masses in live models (with known benign breast masses mapped for location by attending physicians), approx. 37% as compared to students trained by means of a film (25% detection accuracy), live demonstration (19.5% detection accuracy), and those receiving no training at all (23.5% detection accuracy).[27] A similar study using non-medical subjects, demonstrated essentially the same effect: subjects trained on the breast models detected nearly twice as many lesions in live models as compared to subjects receiving no specific training.[24] However, combination model and real tissue training, a

component of Mammatech technology proven to be essential in the acquisition of breast self-examination skills [25], was technically infeasible in the above two studies. Consequently, no study has yet been undertaken to examine critically the potential efficacy of the use of the full Mammatech technology in the training of professionals in breast examination.

The present study was designed to evaluate the clinical efficacy of incorporating the Mammatech technology, already established as a useful method of training women to perform BSE, into the training of medical students in breast examination. Such a study was made possible only because of the highly successful Gynecologic Teaching Assistants Program (see methods) at Yale University School of Medicine.

II. Methods

A. Subjects: Thirty Yale medical students were voluntarily recruited for participation in the study. Sixteen of the students were male, fourteen were female. The majority (24) of the subjects were second-year students, while the remaining students (6) had completed the first year of medical school and participated in the study during the summer prior to their second year. Because of the extra time commitment of the latter group of students, an incentive of $3.00 per patient examined was given to each student at the completion of their participation in the study. The other students were not monetarily compensated for their participation. Prior to their enrollment in the protocol, all students were required to sign written consent forms, and complete a brief questionnaire. Those students with significant experience in breast examination were excluded from the study population. Students were not aware of their group assignment (experimental vs. control) prior to their actual training.

B. Training Sessions: The majority of students in the study received their training in breast examination during the required Gynecologic Teaching Assistants (GTA's) session- a part of the Introduction to Clinical Medicine course offered to second year students. The six first-year students attended GTA sessions specifically arranged for purposes of this study. Training sessions were conducted by six Gynecologic Teaching Assistants (female health professionals employed by the Dept.

of Ob/Gyn to serve as specialized trainers of breast and pelvic examination). All training sessions were conducted in the Ob/Gyn clinic at Yale-New Haven Hospital. Training groups consisted of three medical students with two GTA's: one GTA served as patient-instructor while the other was the observer-instructor, as described below. Control group students received basic instruction in breast examination in accordance with guidelines described by The American Cancer Society [36]. Principles of inspection and palpation were first demonstrated by the GTA's on Betsi Breast**, illustrating the use of the pads of the fingertips, uniform palpation pressure, and concentric circles radiating from the nipple and including the axilla and clavicular area. Students were then given the opportunity to practice these skills individually on the breast tissue of the patient-instructor GTA, while the observer-instructor GTA supervised the student. This training procedure, utilized by the GTA's for the past five years, affords the unique opportunity for the student to receive instructive feedback from the perspective of the patient-instructor, as well as a second observer-instructor.

Experimental group students were also trained in groups of three students per two GTA's, as described above. However, prior to training, these students were administered a 5-minute

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** The Betsi Breast model is produced by Ortho Pharmaceutical Co. The model is constructed of silastic material, and contains implanted "lesions" of uniform size and firmness.

pre-test during which they were asked to examine one of the Mammatech breast models and record their findings. The students were not told how many breast lumps to search for, but only that each model may contain simulated lesion(s). Upon completion of the pre-test, students were asked to correct their test by examining the under-side of the model through which fine simulated lesions are visible. Subsequent to the pre-test, the GTA's demonstrated three major principles of breast examination via the Mammatech technology: 1) discrimination between normal breast tissue nodularity and true lesions, 2) the three palpation pressures: light, medium, and firm with the pads of the fingertips only, and 3) the vertical strip search pattern (extending from the upper axilla down the mid-axillary line to the bra-line and across to the mid-line of the chest with superior extension to the clavicle). Various Mammatech models were used for the demonstraion period, each designed to illustrate specific aspects of the training. As with the control group, students were again allowed to practice the breast examination skills on the breast tissue of the patient-instructor with supervision from the observer-instructor.

In order for students to appreciate the full extent of the tissue that must be palpated in a thorough breast examination, a grid was projected onto the torso of the patient-instructor via an overhead projector. This resulted in a division of the breast tissue into numbered 3 cm. X 3 cm. squares that the student could use as a guide for completing the vertical strip search pattern.

Post-tests on the breast models were conducted in a manner

similar to that described for pre-testing. Each student was given a different model than was used in the pre-test, with a unique pattern of lesions, varying firmness, and background nodularity.

Training sessions lasted no longer than one hour per group, with additional time allotted to experimental group sessions for pre- and post-testing. Students were instructed not to discuss their training sessions with other students outside their group until completion of the study.

C. Clinic Sessions: Subsequent to the GTA training sessions, students were randomly assigned to pairs, each consisting of one control and one experimantal student. Each pair was then assigned to attend a general surgery clinic at the Dana Clinic in Yale-New Haven Hospital. Patients attending the clinic were generally referred by primary care physicians or internists for abnormal breast findings or a history of breast disease.**

After initial screening and examination by the attending physician, patients were asked for their permission to be examined by 2 Yale medical students. Once the patient's verbal consent was obtained by the attending physician, each student was allotted five minutes to examine both breast of the patient. Students were not permitted in the examining room while the attending physician performed his/her breast examination, nor

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** Attending physicians were Dr. Barbara Kinder and Dr. Charles McKhann, both general surgeons with specialization in breast disease. Patients seen in their clinic do not necessarily have abnormal breast findings(some are followed for routine exam only.

were they allowed to observe each other's exams. The only information given to the student prior to examining the patient was the patient's name- no other history or previous physical findings were disclosed. Attending physicians were instructed not to provide students with direction in breast examination, and the patients were also asked not to provide any additional information to the students. If patients inadvertantly disclosed pertinent information, the examination findings were excluded from further analysis.

After completing the breast examination of a patient, each student diagrammed the findings on a standard form (see Appendix II) outlining the clavicles, areolae, axillae, and sternal notch as landmarks. In addition to locating abnormal findings, the students were instructed to describe specific characteristics such as size, texture, mobility, and shape of any lesions detected. If no abnormal findings were discovered, the students were required to report "normal examination". Attending physicians were requested to submit their examination findings on the same standard forms.

III. Results

Overall clinical examination performance of the experimental and control groups were compared using t-tests for correlated means on the following measures: True positive detection frequency, false positive detection frequency, false negative detection frequency, and sensitivity.** The results of these analyses are summarized in Table 1 below.

TABLE I

Summary of Statistical Analysis Based on all Students (N=30)

MEASURE	EXP. MEAN	CONT. MEAN	t	df	p
True Positive	3.93	3.27	1.195	14	not signif
False Positive	4.40	4.20	0.092	14	not signif
False Negative	2.00	2.60	1.348	14	not signif
Sensitivity	0.65	0.64	0.186	14	not signif

Although not statistically significant, mean differences were clearly in the expected direction with experimentally trained students demonstrating a higher true positive detection frequency, lower falsepositive and false negative detection frequencies,

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** Sensitivity is defined by the ratio (a/ a+c) where a=true positives and c= false negatives. (See reference 37)

and a slightly higher sensitivity measure as compared to the control group students.

Despite repeated efforts to standardize the number of patients examined by each pair of students, variations in clinic attendance and appropriateness of patients present at any given clinic led to differences in the number of patient examinations performed by each student. Table II presents a frequency distribution of clinic examinations performed by the fifteen student pairs.

TABLE II

# OF PATIENTS EXAMINED	# OF STUDENT PAIRS
1	2
2	2
3	3
4	5
5	1
6	0
7	1
8	0
9	0
10	1

Since not all students were able to examine a sufficient number of patients to ensure stability in the obtained measures of their skill, the analyses presented in Table I were repeated on the data from those students who performed breast examinations on four or more patients (eight pairs). The results of

these analyses are presented in Table III below.

TABLE III

Summary of Statistical Analysis Based on Students That Performed Four or More Patient Exams (N=16)

MEASURE	EXP. MEAN	CONT. MEAN	t	df	p
True Positive	5.36	3.75	1.879	7	< .10
False Positive	4.38	4.25	0.090	7	not signif.
False Negative	2.88	4.38	2.393	7	< .05
Sensitivity	0.62	0.46	2.895	7	< .05

When the analysis is confined to those measures which are reasonably stable, statistically significant differences emerge favoring the experimentally trained group. These effects are easily visualized graphically in Figure 1 below.

Figure 1

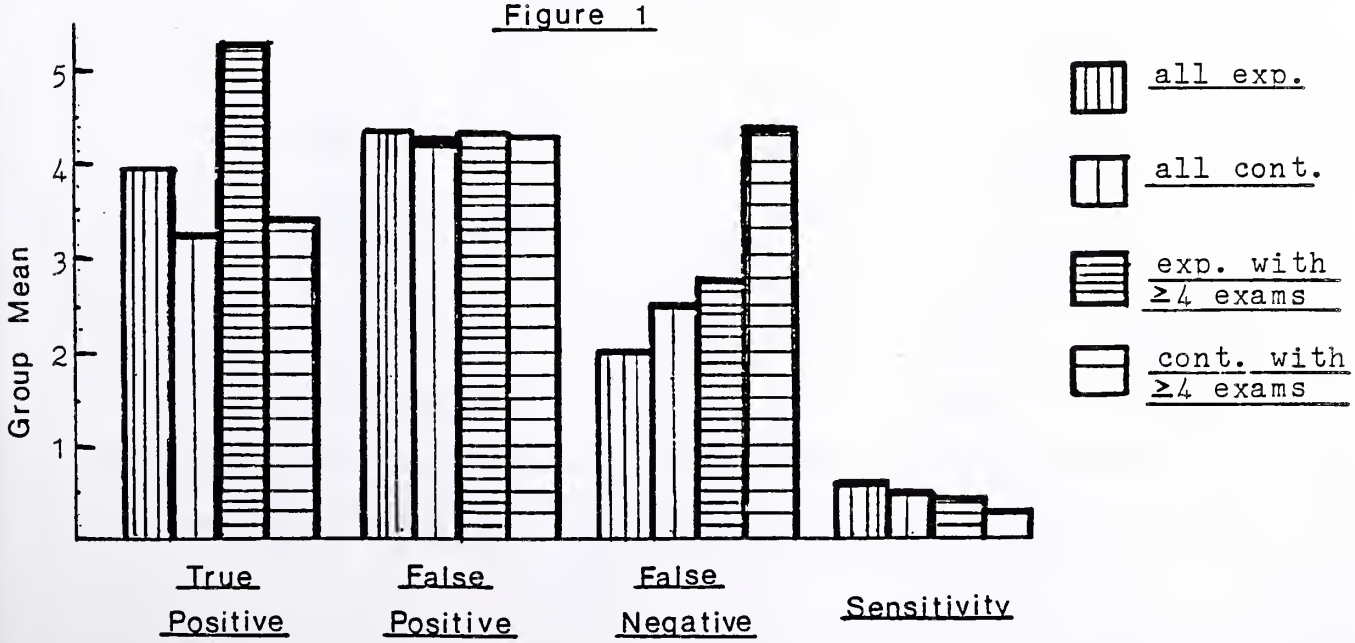


Figure 1 illustrates that the major differences between experimental and control students occur with respect to the true positive and false negative detection frequencies, as well as the sensitivity measures. These differences are magnified when the data from only those students who performed a sufficient number of clinical examinations are considered. Specifically, small differences favoring the experimentally trained students are evident when all of the data are included.

Finally, Table IV consists of data obtained during pre- and post-testing of experimental students (see Methods). although no statistically significant differences in performance were noted, the means demonstrate an improvement in skill as is evident by an increase in true positive detections, and a decrease in false positive and false negative detections.

TABLE IV

Analysis of Pre and Post Test Data (N=15)

MEASURE	PRE-TEST	POST-TEST	t	p
True Positive	3.27	3.87	1.718	not signif.
False Positive	0.60	0.40	0.900	not signif.
False Negative	1.73	1.47	0.576	not signif.

Curiously, the pre-test performance of this group of experimental students is higher than previously reported means [38], and may therefore prevent an accurate assessment of the effects of the GTA training. Clearly, the differences noted in the clinical

performance of students (see Tables I, III, and Figure 1) demonstrate the crucial differences in the effectiveness of training between the two groups.

IV. Discussion

As is demonstrated by the above data, Mammatech technology incorporated into the gynecologic teaching assistant program can be used to train medical students to perform more accurate breast examinations. Students trained in the use of a thorough search pattern, practiced on high-fidelity, realistic human breast models containing simulated lesions, were able to detect a significantly greater number of abnormal breast lesions in the actual clinic setting as compared to students who did not receive such training. In addition, the false negative detection frequency of experimentally trained students was also significantly lower than that of matched controls. As a result, when stable measurements of clinical performance were obtained and analyzed, the sensitivity of breast examinations performed by the experimental group was comparable to that reported for experienced physicians.[22,39] These results raise numerous implications with respect to both future research efforts in breast cancer screening, as well as the training of health care professionals.

One unexpected outcome was the finding that differences in performance between the experimentally trained students and matched controls were significantly greater as the number of patients examined increased. An explanation for this result is suggested by the following anecdotal data: nineteen solitary breast masses were detected in the study population during the course of data collection. Eleven lesions were described

quantitatively, of which seven were greater then 3 cm. in diameter. The overall mean size of lesions detected was 2.9 cm. (see Appendix I). Of the four smaller lesions (mean diameter = 0.75 cm.), three were accurately detected by the experimentally trained student, while only one was found by the control student examining the same patient. In all but one case, the finding was made by students seeing four or more patients in the clinical setting. In other words, students who performed an inadequate number of breast examinations were less likely to encounter smaller lesions than were those who examined at least four patients. This suggests that the Mammacare technology is effective in training the skills necessary to detect smaller breast lesions and that in order to fully demonstrate the sensitivity of the training, students must be given the opportunity to discover smaller, more subtle breast masses. Future investigation of this training method must include a greater percentage of patients with less advanced disease in order to clarify the issues raised by this pilot study.

The data reported also suggest the potential for profound effects of breast cancer screening. In light of 1) the continued controversy concerning the use of mammography in widespread screening of asymptomatic women for breast cancer, and 2) the infrequent and inaccurate performance of BSE among American women, [33-35] the role of the physician (or para professional) in screening breast examinations becomes more crucial.

As can be seen in the data collected on the pre- and post-testing of experimentally trained students, improvement in skill was noted by an increase in true positive detection frequency, as well as a reduction in both false positive and false negative detection frequencies. However, mastery of the skills was not obtained in this pilot study. One can only speculate about the potential reductions in morbidity and mortality from breast cancer if all professionals were trained to proficiency in the Mammatech technology. Given that a post-test true positive detection frequency of 3.87 correlates with a sensitivity of 62% in the clinical setting, a professional trained to a maximum proficiency level (5.0 in the model series used in this study) on the breast models could theoretically perform clinical examinations with an 80% sensitivity rate. Since the role of routine physician examination in breast cancer screening remains a crucial part of our efforts to reduce the morbidity and mortality of the disease, we are obligated to provide professionals with the skills essential to the accurate performance of this task. The above data present encouraging evidence to suggest that a technology is now available to enhance the ability of professionals to perform this critical, and potentially life-saving function.

TRUE PHYSICAL FINDINGS

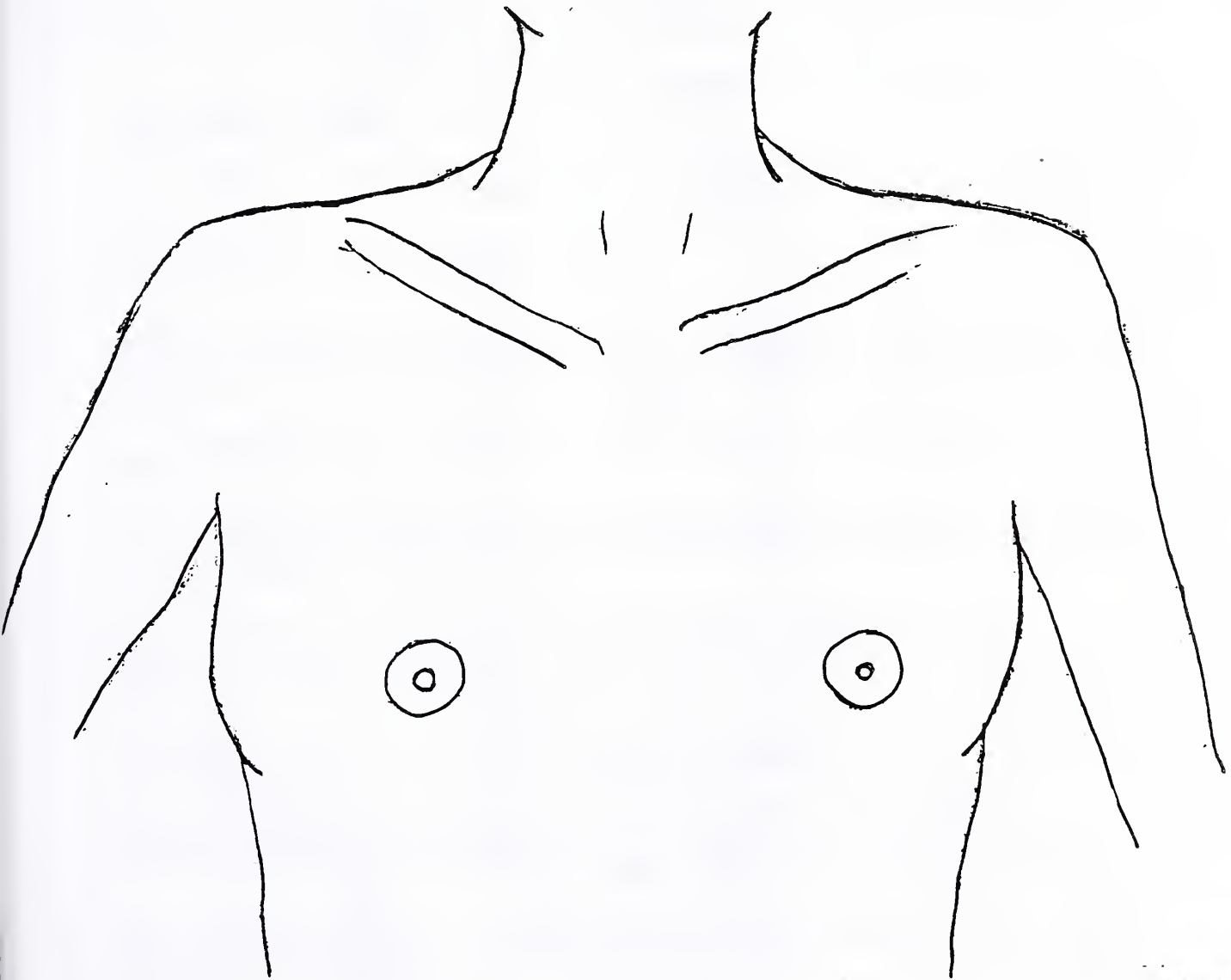
(findings noted by attending- to biopsy or surgery)

Pt. #	Found by Exp. Student	Found by Cont. Student	Size
1	YES	YES	3.0 x3.0 cm.
2	YES	YES	"pea size"
3	YES	YES	not specified
4	YES	YES	5.0 cm.-cyst
5	YES	YES	3.0 x3.0 cm.
6	YES	YES	2.0 x3.0 cm.
7	YES	YES	2.0 x3.0 cm.
8	YES	YES	3.0 x4.0 cm.
9	YES	YES	2.0 x3.0 cm.
10	YES	YES	1.5 cm.-cyst
11	YES	YES	not specified
12	YES	YES	not specified
13	NO	YES	0.5 cm.-cyst
14	YES	YES	not specified
15	YES	YES	1.0 cm.
16	YES	NO	"bee-bee sized"
17	YES	NO	0.5 cm.
18	YES	NO	1.5 cm
19	YES	NO	"plaque"

Patients name: _____

Attending physician: _____

Your name: _____



Specific description of findings (if any) =
(size, location, texture)

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